

K072091

510(k) SUMMARY

007 2 9 2007

SUBMITTER: Sorin Group Italia S.r.l.
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DATE PREPARED: July 27, 2007

DEVICE TRADE NAME: **D101 KIDS** Infant Hollow Fiber Membrane
Oxygenator with Integrated Hardshell
Cardiotomy/Venous Reservoir with phosphorylcholine
coating (Ph.I.S.I.O. coating)

COMMON NAMES: Hollow Fiber Membrane Oxygenator with Hardshell
Cardiotomy/Venous Reservoir
Hollow Fiber Oxygenator
Hardshell Cardiotomy/Venous Reservoir

CLASSIFICATION NAMES: Cardiopulmonary Bypass Oxygenator
Cardiopulmonary Bypass Heat Exchanger
Cardiopulmonary Bypass Blood Reservoir
Cardiopulmonary Bypass Defoamer

PREDICATE DEVICES: D902 Lilliput 2 with Phospholipidic Inert Surface In
Oxygenation (Ph.I.S.I.O.) Infant Hollow Fiber
Oxygenator (K001021)

D100 L001 Ph.I.S.I.O. Newborn Hollow fiber
Membrane Oxygenator with Integrated Hardshell
Cardiotomy/Venous Reservoir with phosphorylcholine
coating (K061031)

DEVICE DESCRIPTION:

The D101 KIDS Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir with phosphorylcholine coating (hereafter referred to as the D101 KIDS) is a high efficiency infant microporous hollow fiber membrane oxygenator integrated with an heat exchanger and connected to an hardshell cardiotomy/venous reservoir. The device is a modified version of the currently marketed D902 Lilliput 2 Ph.I.S.I.O (K001021) predicate device (hereafter referred to as the D902 Ph.I.S.I.O.). The modification is limited to an overall reduction in the size of the device, design change to the integrated heat exchanger and hardshell venous cardiotomy/venous reservoir, and consequent updating of product specifications in the IFUs with the inclusion of vacuum assisted venous drainage in the Intended use. The reduction in size enables the device to be better suited for the infant patient population.

INDICATION FOR USE:

The D101 KIDS Infant Hollow Fiber Membrane Oxygenator With Integrated Hardshell Cardiotomy/Venous Reservoir, is a sterile, nonpyrogenic device intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 2.5 liters/minute. It provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia, or aids in the maintenance of normothermia during surgery. The venous reservoir is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. The D101 KIDS should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The D101 KIDS is an infant cardiopulmonary bypass of hollow fiber design with heat exchanger and integrated hardshell cardiotomy/venous reservoir similar to the D902 Ph.I.S.I.O. predicate device. Both devices are identical with respect to materials, biocompatibility of the PmMI₂ coating, operating principles, technological characteristics and manufacturing process. The D101 KIDS oxygenating module shares the same basic design, operating principles and control mechanisms of the D902 Ph.I.S.I.O. module, but is reduced in size. The only modification consists of a heat exchanger design revision with increased surface area with respect to the D902 Ph.I.S.I.O. In addition, the D101 KIDS shares identical design philosophy and fundamental scientific technology with the D100 Ph.I.S.I.O. newborn oxygenator predicate device, consisting of a packed oxygenating module of reduced dimensions which accommodates a heat exchanger of the same optimized geometry. The hardshell cardiotomy/venous reservoir present in both D101 KIDS and D902 Ph.I.S.I.O. share the same single chamber design, technological characteristics, operating principles and materials except for the revised filtering system design and overall reduced dimensions of the housing. In addition, the intended use of the device has been expanded to include the use of vacuum assisted venous drainage. These changes make the D101 KIDS reservoir consistent with technology implemented in existing oxygenators manufactured by Sorin Group Italia like the D100 Ph.I.S.I.O. predicate device. An overall reduction of its dimensions with consequent less hollow fiber material and reduced priming volume as well as some external features revision, characterize the D101 KIDS as compared to the D902 Ph.I.S.I.O.. These differences make the D101 KIDS more suited for infant patients like the D902 Ph.I.S.I.O. predicate device. The D101 KIDS is substantially equivalent to the D902 Ph.I.S.I.O. predicate device in intended use, patient population and performance specifications.

The coating of the oxygenating module is identical to the phosphorylcholine coating used on the D902 Ph.I.S.I.O. predicate device.

The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:2003 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the D100 Ph.I.S.I.O. (accelerated aging). The aged device was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of this testing met established specifications. As no new materials are used in the D101 KIDS infant oxygenator with respect to the D100 Ph.I.S.I.O., data collected are considered applicable to the D101 KIDS oxygenator.

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 - "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission"

Final Guidance for industry and FDA issued on November 29, 2000 – “Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission” Final Guidance for industry and FDA issued on November 29, 2000 and when applicable, following the ISO 7199 (1996) standard for “Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)” for providing the data necessary to demonstrate both the substantial equivalence with the predicate devices and also complying with safety and effectiveness requirements. The device aged up to 3 (+1 year considered as worst case) years was tested for gas transfer characteristics, pressure drop, plasma leakage data, operating blood volumes, heat exchanger performance evaluation, hemolysis/cell depletion, mechanical integrity, venous cardiotomy reservoir characterization (including breakthrough times and volumes, reservoir graduated scale accuracy, residual blood volume, defoaming capacity, filtration efficiency and reservoir housing integrity) and leaching studies characterization. The results of these tests met established specifications. For comparison purposes, the same testing, when applicable, has been conducted also on the D902 Ph.I.S.I.O. predicate device.

The results of the study showed that the device is comparable to the predicate devices concerning all characteristics.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the D101 KIDS performs in a manner substantially equivalent or sometimes better than (e.g reduced operating blood volumes, breakthrough time and volume and improved heat exchanger efficiency) the D902 hollow fiber oxygenator with respect to the relevant functional parameters. This is in line with our expectations, as the D101 KIDS is smaller in overall size, has a more compact design, and contains a different heat exchanger /reservoir filtering system design as compared to the D902 Ph.I.S.I.O. predicate device. Although these design differences affect the above performance parameters, they are intended to make the D100 Ph.I.S.I.O. more suitable for use on infant patients. The smaller size offers theoretical advantages in terms of reduced priming volume and consequently less hemodilution. A lower priming volume is desirable as it results in advantageous patient hemodynamics, reduced exposure of the blood cells and plasma proteins to large surface areas and reduced need for transfusion, which has the potential risk of donor transmitted disease. Furthermore, the D101 KIDS performs in a manner substantially equivalent to the D902 Ph.I.S.I.O with respect to biocompatibility, according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to insure that the oxygenator is sterile and non-pyrogenic



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

007 2 9 2007

Sorin Group Italia, S.r.l.
c/o Mr. Barry Sall
Principal Consultant
Parexel Consulting
200 West Street
West Street, Waltham, MA 02451-1163

Re: K072091
D101 KIDS Hollow Fiber Membrane Oxygenator with Integrated Hardshell
Cardiotomy/Venous Reservoir with Ph.I.S.I.O. coating
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenators
Regulatory Class: Class II
Product Code: DTZ
Dated: July 27, 2007
Received: July 30, 2007

Dear Mr. Sall:

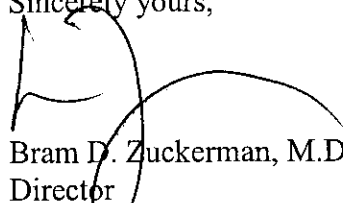
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the printed name and title.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: D101 KIDS Infant Hollow Fiber Membrane Oxygenator with Integrated Hardshell
Cardiotomy/Venous Reservoir with phosphorylcholine coating (Ph.I.S.I.O. coating)

The D101 KIDS Infant Hollow Fiber Membrane Oxygenator is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 2.5 liters/minute. It provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation, to always assure the proper oxygenation capability of the device. The D101 KIDS should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Device Name: D101 KIDS Infant Hollow Fiber Membrane Oxygenator with phosphorilcholine coating
(Ph.I.S.I.O. coating)

The D101 KIDS Infant Hollow Fiber Membrane Oxygenator is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 2.5 liters/minute. It provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The D101 KIDS should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Device Name: D121 KIDS Infant Hardshell Cardiotomy/Venous Reservoir with phosphorilcholine coating
(Ph.I.S.I.O. coating)

D121 KIDS HVR has been specifically designed for cardiovascular procedures requiring cardiopulmonary by-pass. It collects venous blood and it defoams, filters and stores the blood from the operating field through thoracic, intracardiac and general suction. The D121 KIDS HVR should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K072051